UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|------------------------|---------------------|------------------|
| 10/587,086 | 07/21/2006 | Magali Bourghol Hickey | CP404A | 9530 |
| 27573 Ross J. Oehler | 7590 05/07/200 | 9 | EXAM | INER |
| CEPHALON, Inc. 41 MOORES ROAD PO BOX 4011 | | | KUMAR, SHAILENDRA | |
| | | | ART UNIT | PAPER NUMBER |
| FRAZER, PA 1 | 19355 | | 1621 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/07/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) |
|---|---|--|
| | 10/587,086 | HICKEY ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | SHAILENDRA KUMAR | 1621 |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DOWN - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period vortice and the reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |
| Status | | |
| Responsive to communication(s) filed on 21 Ju This action is FINAL . 2b) ☑ This Since this application is in condition for alloware closed in accordance with the practice under E | action is non-final. | |
| Disposition of Claims | | |
| 4) ☐ Claim(s) <u>1-30</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) <u>1-30</u> are subject to restriction and/or expressions. | wn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and all accomposed and all all all all all all all all all al | epted or b) objected to by the Edrawing(s) be held in abeyance. See iion is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)). | on No ed in this National Stage |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate |

Application/Control Number: 10/587,086 Page 2

Art Unit: 1621

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 13(part), 14, 20(part)-21(part), drawn to compositions comprising 2:1 R:S modafinil, their synthesis and method of treatment using them.

Group II, claim(s) 4-6, 13(part), 15, 20(part)-21(part), 22, drawn to R-(-)-modafinil Form III.

Group III, claim(s) 7-9, 13(part), 17, 20(part)-21(part), 28-30, drawn to R-(-)-modafinil Form V, preparation and method of use.

Group IV, claim(s) 10-12, 13(part), 16, 20(part)-21(part), 27, drawn to R-((-)-modafinil Form IV, preparation and use.

Group V, claim(s) 23(part)-26(part), drawn to chloroform solvate.

Group VI, claim(s) 23(part)-26(part), drawn to chlorobenzene solvate.

Group VII, claim(s) 23(part)-26(part), drawn to acetic acid solvate.

- 2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The only linking concept among the different independent claims are crystalline forms of modafinil and their enantiomers, that are already state of the art(see for example EP 233106 or WO 02/10125) together with their use for the treatment of narcolepsy. This feature is therefore not a special technical feature in the sense of Rule 44EPC..
- 3. In view of the complex nature of the restriction requirement, a written restriction requirement has been made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

Application/Control Number: 10/587,086 Page 3

Art Unit: 1621

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/587,086 Page 4

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHAILENDRA - KUMAR/ Primary Examiner, Art Unit 1621

S. Kumar 5/4/09